K093313

## 510(k) SUMMARY

DEC - 2 2009

**Topcon Medical Systems, Inc.**
**Synergy**

### Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

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Date Prepared: September 14, 2009

### Name of Device and Name/Address of Sponsor

Synergy
Topcon Medical Systems, Inc.
37 West Century Road
Paramus, NJ 07652

### Common or Usual Name

System, image management, ophthalmic

### Classification Name

21 C.F.R. 892.2050

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System, image management, ophthalmic

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**Predicate Devices**

Topcon Corporation IMAGEnet Professional PC Software System (K082364)
Nidek Advanced Vision Information System (NAVIS) (K013694)
Digital Healthcare, Ltd. Oculab IP (K071299)
Topcon Corporation 3D OCT-1000 (K072971)

**Intended Use / Indications for Use**

Synergy is a comprehensive software platform intended for use in acquisition or importing, processing, measurement, analysis and storage of clinical images and videos of the eye as well as in management of patient data, diagnostic data, clinical information, reports from ophthalmic diagnostic instruments through either a direct connection with the instruments or through computerized networks.

**Technological Characteristics**

Synergy is a software platform that collects, processes, measures, analyzes, stores, and manages patient data and clinical information. Synergy is used together with a number of computerized digital imaging devices. In addition, Synergy software collects and manages patient demographics, image data, and clinical reports from a range of approved medical devices. Synergy enables a real-time review of diagnostic patient information at a PC workstation. In addition to the desktop application, Synergy also includes an internet-browser-based user interface to allow authorized users to access, view, create reports, and analyze patient and examination data saved in a centralized database. The system utilizes dual level authentication and 128-bit encryption to ensure secure networking environment.

## Performance Data

No performance data was required or provided. Software validation and verification demonstrate that the Synergy performs as intended and meets its' specifications.

## Substantial Equivalence

Synergy is as safe and effective as the identified predicate devices including Topcon Corporation's IMAGEnet Professional PC Software System (K082364), Nidek's Advanced Vision Information System (NAVIS) (K013694), Digital Healthcare's Oculab IP (K071299) and Topcon Corporation's 3D OCT-1000 (K072971). Synergy has the same intended uses and similar indications, technological characteristics, and principles of operation as its predicate devices. Both Synergy and the predicate devices have similar technological characteristics. Synergy and all the identified predicate devices with the exception of the Topcon 3D OCT-1000 are software only devices.

Capturing devices for Synergy are OCT, mydriatic and non-mydriatic retinal cameras and slit lamps which are similar to the other predicate devices. Topcon Corporation's IMAGEnet Professional PC Software System, Digital Healthcare's Oculab IP and Nidek's Advanced Vision Information System (NAVIS) all allow capture with mydriatic and non-mydriatic retinal cameras and slit lamps. The 3D OCT-1000 captures images with OCT.

Synergy, Digital Healthcare's Oculab IP, Topcon Corporation's IMAGEnet Professional PC Software System and Nidek's Advanced Vision Information System (NAVIS) all allow importing and management of files and images from a range of ophthalmic diagnostic devices including DICOM files, image files of known format, and video images. Synergy and the Digital Healthcare, Ltd. Oculab IP both also allow import of printer files.

In regards to measurement and analysis functions, Synergy, Digital Healthcare's Oculab IP, Topcon Corporation's IMAGEnet Professional PC Software System and Nidek's Advanced Vision Information System (NAVIS) all perform line/area measurements of retinal images. Additionally, Synergy and Topcon's 3D OCT-1000 both provide OCT retinal and RNFL thickness measurements functions.

In conclusion, Synergy shares similar technological characteristics as the predicate devices, both in terms of the manner in which images are captured, analyzed, and

stored, as well as the operation of the device by the intended user. Any minor differences in operation do not raise new questions of safety and effectiveness. Synergy raises the same issues of safety and effectiveness as the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room – WO66-G609
Silver Spring, MD 20993-0002

Topcon Medical Systems, Inc.
% Mr. Tamas Borsai
Division Manager, Medical Division
TÜV Rheinland of North America
12 Commerce Road
NEWTOWN CT 06470

DEC - 2 2009

Re: K093313
Trade/Device Name: Synergy
Regulation Number: 21 CFR 892.2050
Regulation Name: Picture archiving and communications system
Regulatory Class: II
Product Code: NFJ and LLZ
Dated: November 19, 2009
Received: November 23, 2009

Dear Mr. Borsai:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical

device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

Janine M. Morris
Acting Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

## Indications for Use Statement

510(k) Number (if known): K093313

Device Name: Synergy

Indications for Use:

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Prescription Use ___X__ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE -- CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and
Radiological Devices
510(k) Number K093313